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| 10/726,199      | 12/01/2003  | Barbara Chapman      | PP00048.252         | 3463             |

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/726,199

Applicant(s)

CHAPMAN ET AL.

Examiner

Agnes B Rooke

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 20-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1 Oct. 2003</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 1-36 are pending.

Applicant's election of Group I, Claims 1-19 without traverse filed on February 23, 2005 is acknowledged. Claims 1-19 are currently under examination.

The instant application is a CIP of 06/822,989, filed on 01/27/1986, now abandoned, to which the priority is claimed.

### ***Objections***

In Claim 2 the phrase "5 number%" must be corrected.

In specification, page 8, line 10, correct "5 number%"

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 does not have sequences of first polynucleotide encoding first signal sequence or first region or second polynucleotide or second polypeptide. Therefore, the structure of the polynucleotides or polypeptides does not correlate with its function.

In Claim 8, the structure of polypeptide spacer, second region, and first polypeptide is not provided, therefore the structure does not correspond with its function. Also, in Claim 8 the structure of polypeptide spacer is of "about 3 to about 100 amino acids which has fewer than 5 sites of N-linked glycosylation." There could be many variations of the same sequence since the number of amino acids is undefined, and thus the structure of the protein does not correspond with its function.

In Claim 10, the structure of the polypeptide spacer is not provided, and the claim states that the spacer comprises peptide homologous to a human Ig heavy chain hinge region. According to a common understanding, homology means that proteins look similar and work in similar ways. Because the structure of the spacer or Ig is not provided, the structure of the peptide does not correspond with its function.

In Claim 14, the structure of the second sequence must be provided ( $\alpha$ 1-antitrypsin), since the structure of the peptide does not correspond with its function.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 does not disclose a sequence of the first polypeptide or second polypeptide or first signal sequence or first region, and proper SEQ IDs are not assigned to the corresponding polynucleotides and polypeptides. Also, the terms "homologous to the A domain" and "homology to the C domain" are indefinite.

In Claim 2, the term "more than about" is indefinite.

In Claims 3-9, 11, 12, 13, 15, 16, the SEQ ID NOs must be assigned to the appropriate amino acid sequence, otherwise examiner cannot interpret and examine the claims.

In Claim 8, the structure of polypeptide spacer is indefinite since the language of the claim states that spacer is of "about 3 to about 100 amino acids which has fewer than 5 sites of N-linked glycosylation." It is not clear what defines the N-terminal sequence of the B domain of human Factor VIII, because for example, it could be anything less than the C-terminal. Further, it is not clear what defines the C-terminal sequence of the B domain of human Factor VIII. Also, disclosure of the amino acid structure of the B domain is necessary, since otherwise the invention is indefinite.

In Claim 14, the amino acid structure of the  $\alpha$ 1-antitrypsin must be provided, since otherwise the invention is indefinite.

Claim 15 has improper dependency, since it depends from Claim 4. Claim 15 refers to "said  $\alpha$ 1-antitrypsin signal sequence," however Claim 4 does not refer to  $\alpha$ 1-antitrypsin signal sequence. The claim's dependency should be corrected.

Claim 19 has improper dependency, since it depends from Claim 8. Claim 19 refers to the first polynucleotide and second polynucleotide that are in separate plasmids, however Claim 8 refers to polypeptide and a spacer. The claim's dependency should be corrected.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 10, 11, 14, and 16-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9, 11, 13-17, and 22 of the of U.S. Patent No. 5,789,203. Although the conflicting claims are not identical, they are not patentably distinct from each other because the aforementioned claims are identical and refer to a similar invention.

***Prior art of record***

1. Wood et al., Expression of Active Human Factor VIII from Recombinant DNA Clones, Nature, (1984) 312, 22 Nov., p. 330-336. Wood et al. describe DNA clones encoding the complete amino acid sequence for human factor VIII that has been isolated and used to produce biologically active Factor VIII in cultured mammalian cells. See Abstract; Figure 3; Figure 4; page 334, right paragraph in the middle. On page 336, right paragraph, Wood et al. characterized A, B and C domains in Factor VIII, and concluded that removal of the unique B domain, which connects the 90kDa, and 80kda fragments is associated with activation of the protein. Wood et al. do not teach deletion of at least a portion of the B domain or co-expression of the light and heavy chains.

2. Truett et al., Characterization of the Polypeptide Composition of Human Factor VIII:C and the Nucleotide Sequence and Expression of the Human Kidney cDNA, (1985), DNA, vol. 4, p. 333-349, teach the structure of human Factor VIII. See Figures 7 and 8, page 342-343.


**Conclusion**

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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**KAREN COCHRANE CARLSON, PH.D**  
**PRIMARY EXAMINER**